OIPE
DEC 19 2003
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ilan et al

Serial No. 10/733,488 Group Art Unit: Not yet assigned

Filed: December 10, 2003 Examiner: Not yet assigned

Title: REGULATION OF IMMUNE RESPONSE BY MANIPULATION OF INTERMEDIARY METABOLIT LEVELS

TRANSMITTAL
INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement which is being filed in accordance with 37 C.F.R. §§ 1.56 and 1.97-1.98. The items listed on Form PTO-1449, a copy of which is enclosed, may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No.: EL647884380US
Deposit Date: December 19, 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

DEC 19 2003

Ronald C. Fedus **Date**
Reg. Exhibit 32,567

Enz-64(D3)

1. [] For each of the following items listed on the enclosed copy of Form PTO-1449 that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:

2. [] For each of the following items listed on the enclosed copy of form PTO-1449 that is not in the English language, a concise explanation of the relevance of that item is incorporated in the specification of the above-identified application.

3. [] Any copy of the items on the enclosed copy of Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in the prior [] Divisional or [] Continuation-In-Part application under 37 C.F.R. §1.60, U.S. Serial No. _____, filed _____.

4. [] No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with:

 [] 37 C.F.R. §1.97(b)(1), within three months of the filing date of the above-identified application.

 [] 37 C.F.R. §1.97(b)(2), within three months of the date of entry into the national stage as set forth in ∋1.491 in an international application.

 [] 37 C.F.R. §1.97(b)(3), before the mailing date of a first Office action on the merits.

5. [] No fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a Notice of Allowance (where there has been no prior final action), and is accompanied by one of the certifications pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below.

6. [x] A fee is due under 37 C.F.R. §1.17(p) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(c), after the period specified in paragraph 4 above but before the mailing date of a final action or a notice of allowance (where there has been no prior final action):

 [] A check in the amount of $180.00 is enclosed in payment of the fee.

[x] Charge the fee to Deposit Account No. 05-1135, Order No. **Enz-64(D3).** A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

7. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with 37 C.F.R. §1.97(d), after the mailing date of a final action or a notice of allowance, whichever comes first, but before payment of the issue fee, and is accompanied by:

 a. one of the certification pursuant to 37 C.F.R. §1.97(e) set forth in paragraph 9 below; and

 b. the attached petition requesting consideration of this Information Disclosure Statement; and

 c. the fee due under 37 C.F.R. §1.17(i)(1) which is paid as set forth in paragraph 10 below.

8. [] A fee is due under 37 C.F.R. §1.17(i)(1) for this Information Disclosure Statement since it is being filed in compliance with:

 a. [] 37 C.F.R. §1.313(b)(3), after the issue fee has been paid and information cited in this Information Disclosure Statement may render at least one claim unpatentable and is accompanied by the attached Petition To Withdraw Application From Issue;

 b. [] 37 C.F.R. §1.313(b)(5), after the issue fee has been paid and information cited in this Information Disclosure Statement is to be considered in a Continuation application upon abandonment of the instant application and is accompanied by the attached Petition To Withdraw Application From Issue.

 c. [] The fee due under 37 C.F.R §1.17(i)(1) is paid as set forth in paragraph 10 below.

9. [] I hereby certify that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

 [] I hereby certify that no item of information in the Information Disclosure Statement filed herewith was cited in a communication from a foreign patent office in a counterpart foreign application or, to my knowledge after making reasonable inquiry, was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

10. [] A check in the amount of $180.00 is enclosed in payment of the fee due under 37 C.F.R. §1.17(i)(1).

[X] Charge the fee under 37 C.F.R. §1.17(i)(1) to Deposit Account No. 05-1135. Order No. **Enz-64(D3).** A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

[x] The Commissioner is hereby authorized to charge any additional fees which may be required for this Information Disclosure Statement, or credit any overpayment to Deposit Account No. 05-1135. A DUPLICATE COPY OF THIS SHEET IS ATTACHED.

Respectfully submitted,

Dated: December 19, 2003

By: _____
Ronald C. Fedus
Registration No. 32,567

Mailing Address:

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JC105
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Ilan et al

Serial No. 10/733,488

Filed: December 10, 2003

Title: **REGULATION OF IMMUNE RESPONSE BY MANIPULATION OF INTERMEDIARY METABOLIT LEVELS**

Group Art Unit: Not yet assigned
(Parent Group Art Unit: 1648)

Examiner: Not yet assigned
(Parent Examiner: Emily M. Le)

527 Madison Avenue, 9th Floor
New York, New York 10022
December 19, 2003

FILED VIA EXPRESS MAIL

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §§1.56 & 1.971.98

Dear Sirs:

Pursuant to the provisions of 37 C.F.R. §§1.971.98, and in full compliance with their duty of disclosure under 37 C.F.R. §1.56, Applicants, through their attorney, are bringing the following eighteen (18) documents to the attention of the U.S. Patent and Trademark Office and the Examiner handling their above-identified application:

EXPRESS MAIL CERTIFICATE

"Express Mail" Label No.: EL647884380US
Deposit Date: December 19, 2003

I hereby certify that this paper and the attachments herein are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.110 on the date indicated above and is addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

DEC 19 2003

Ronald C. Fedus
Reg. Exhibit 32,567

Date

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1. Schoenfeld, Y., et al, "Gaucher's disease: a disease with chronic stimulation of the immune system," Arch Pathol Lab Med 106(8):388-391 (1982) **[Exhibit 1]**;

2. Lichtenstein, et al, "Cytokine mRNA in Gaucher Disease," Blood Cells, Molecules and Diseases 23(19):395-401 (1997) **[Exhibit 2]**;

3. Barak, V., et al, "Cytokines in Gaucher's Disease," Eur. Cytokine Netw. 10(2):205-210 (1999) **[Exhibit 3]**;

4. Hollak, CEM, et al, "Elevated Levels of M-CSF, sCD14 and IL8 in Type 1 Gaucher Disease," Blood Cells, Molecules and Diseases 23(11):201-212 (1997) **[Exhibit 4]**;

5. Allen, MJ, et al, "Pro-inflammatory cytokines and the pathogenesis of Gaucher's disease: increased release of interleukin-6 and interleukin-10," Q. J. Med. 90(1):19-25 (1997) **[Exhibit 5]**;

6. Deibener, J., et al, "Enzyme replacement therapy decreases hypergammaglobulinemia in Gaucher's disease," Haematologica 83:479-480 (1998) **[Exhibit 6]**;

7. Lachman, et al, "Massive hepatic fibrosis in Gaucher's disease: clinico-pathological and radiological features," Q. J. Med 93:237-244 (2000) **[Exhibit 7]**;

8. Kawano, et al, "CD1d-Restricted and TCR-Mediated Activation of V_a14 NKT Cells by Glycosylceramides," Science 278:1626-1629 (1997) **[Exhibit 8]**;

9. Burdin, N., et al, "Selective Ability of Mouse CD1 to Present Glycolipids: $_a$-Galactosylceramide Specifically Stimulates V_a14^+ NK T Lymphocytes," J. Immunol 161:3271-3281 (1998) **[Exhibit 9]**;

10. Roy-Chowdhury, et al, U.S. Patent Application Serial No. 08/808,629 filed February 28, 1997 **[Exhibit 10]**;

11. Roy-Chowdhury, et al, U.S. Patent Application Serial No. 09/356,294 filed on July 16, 1999, specification subsequently published in U.S. Patent Application No. 2003-0170258-A1, published September 11, 2003 **[Exhibit 11]**;

12. Rabbani, et al, European Patent Application 1 072 271 A2, published January 31, 2001 **[Exhibit 12]**;

13. Hollak, et al, "Marked elevation of plasma chitotriosidase activity. A novel hallmark of Gaucher disease," J. Clin. Invest. 93(3):1288-1292 (1994) **[Exhibit 13]**;

14. Ferrari, C., et al, "Immunopathogenesis of hepatitis C virus infection," J. Hepatol 31s1:31-38 (1999) **[Exhibit 14]**;

15. Cerny, A., et al, "Pathogenesis of chronic hepatitis C: immunological features of hepatic injury and viral persistence," Hepatology 30(3):595-601 (1999) **[Exhibit 15]**;

16. Rehermann, B., "Cellular immune response to the hepatitis C virus," J. Viral Hepat. 6s1:31-35 (1999) **[Exhibit 16]**;

17. Gotsman, I., et al, "Induction of oral tolerance towards hepatitis B envelope antigens in a murine model," Antiviral Research 48:17-26 (2000) **[Exhibit 17]**;

18. Akbar, SM, et al, "Low responsiveness of hepatitis B virus-transgenic mice in antibody response to T-cell-dependent antigen: defect in antigen presenting activity of dendritic cells," Immunology 78(3):468-475 (1993) **[Exhibit 18]**;

The eighteen (18) foregoing references (numbers 1-18) were cited in the specification of the instant application.

A completed Form PTO-1449 listing the 18 above-submitted documents is also attached hereto as Exhibit 19.

By this voluntary citation of art, Applicants and their attorney are requesting that the documents be made of record in the present application.

The above citation of documents is not a representation that these documents constitute a complete or exhaustive listing, nor that the above listing necessarily includes the closest or most relevant documents, nor are these documents necessarily a complete listing of all documents known to Applicants or their attorney. It is simply a voluntary citation of documents made in good faith,

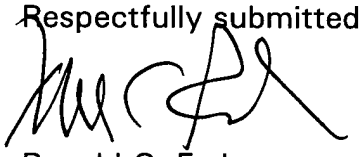
which is not intended to serve in any way as a substitute for the Examiner's own search.

In view of the general and specific features described and claimed in the present application, Applicants respectfully submit that the present invention is neither disclosed nor suggested by the documents referred to above and is thus patentably distinct thereover. Furthermore, Applicants do not believe, and do not submit, by the citation of these references, that these documents, either by themselves or in combination with other documents, render the invention *prima facie* obvious under the duty of disclosure rules.

Applicants respectfully request that the Examiner make the above-submitted documents of record in the instant application. Applicants further request that the Examiner consider these documents as any of them may relate to the instant application.

The fee under 37 C.F.R. §1.17(p) for filing this Information Disclosure Statement is $180.00. The Patent and Trademark Office is hereby authorized to charge the amount of this fee (and any other fees in connection with this IDS) to Deposit Account No. 05-1135, or to credit any overpayment thereto.

Respectfully submitted,



Ronald C. Fedus
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Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office INFORMATION DISCLOSURE CITATION (use several sheets if necessary)	Atty. Docket No. ENZ-64(D3)	Serial No. 10/733,488
	Applicants: Ilan, et al	
	Filed: Dec. 10, 2003	Group: Not yet assigned

OIPE JC105 DEC 19 2003 PATENT & TRADEMARK OFFICE

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO-PRIATE
	10	3 7 7 6 2 8		Roy-Chowdhury, et al			3/4/03
		0 1 7 0 2 5 8	9/11/03	Roy-Chowdhury, et al	A1		

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	TRANS-LATION YES	NO
	EP	1 0 7 2 2 7 1	1/31/01	Rabbani, et al	A2			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Schoenfeld, Y., et al, "Gaucher's disease: a disease with chronic stimulation of the immune system," Arch Pathol Lab Med 106(8):388-391 (1982)
		Lichtenstein, et al, "Cytokine mRNA in Gaucher Disease," Blood Cells, Molecules and Diseases 23(19):395-401 (1997)
		Barak, V., et al, "Cytokines in Gaucher's Disease," Eur. Cytokine Netw. 10(2):205-210 (1999)
		Hollak, CEM, et al, "Elevated Levels of M-CSF, sCD14 and IL8 in Type 1 Gaucher Disease," Blood Cells, Molecules and Diseases 23(11):201-212 (1997)
		Allen, MJ, et al, "Pro-inflammatory cytokines and the pathogenesis of Gaucher's disease: increased release of interleukin-6 and interleukin-10," Q. J. Med. 90(1):19-25 (1997)
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		Lachman, et al, "Massive hepatic fibrosis in Gaucher's disease: clinico-pathological and radiological features," Q. J. Med 93:237-244 (2000)
		Kawano, et al, "CD1d-Restricted and TCR-Mediated Activation of V_a14 NKT Cells by Glycosylceramides," Science 278:1626-1629 (1997)
		Burdin, N., et al, "Selective Ability of Mouse CD1 to Present Glycolipids: $_a$-Galactosylceramide Specifically Stimulates V_a14^+ NK T Lymphocytes," J. Immunol 161:3271-3281 (1998)

EXAMINER	**DATE CONSIDERED**

***EXAMINER**: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Form PTO-1449 U.S. Department of Commerce (REV. 8-83) Patent and Trademark Office INFORMATION DISCLOSURE CITATION (use several sheets if necessary)	Atty. Docket No. ENZ-64(D3)	Serial No. 10/733,488
	Applicants: Ilan, et al	
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPRO-PRIATE

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	TRANS-LATION YES	TRANS-LATION NO

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

		Hollak, et al, "Marked elevation of plasma chitotriosidase activity. A novel hallmark of Gaucher disease," J. Clin. Invest. 93(3):1288-1292 (1994)
		Ferrari, C., et al, "Immunopathogenesis of hepatitis C virus infection," J. Hepatol 31s1:31-38 (1999)
		Cerny, A., et al, "Pathogenesis of chronic hepatitis C: immunological features of hepatic injury and viral persistence," Hepatology 30(3):595-601 (1999)
		Rehermann, B., "Cellular immune response to the hepatitis C virus," J. Viral Hepat. 6s1:31-35 (1999)
		Gotsman, I., et al, "Induction of oral tolerance towards hepatitis B envelope antigens in a murine model," Antiviral Research 48:17-26 (2000)
		Akbar, SM, et al, "Low responsiveness of hepatitis B virus-transgenic mice in antibody response to T-cell-dependent antigen: defect in antigen presenting activity of dendritic cells," Immunology 78(3):468-475 (1993)

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